

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mersereau on 10/28/2010

The application has been amended as follows:

In the Claims

- The listing of claims will replace all prior versions, and listings, of claims in the application.

1-59 (Canceled).

60. A disposal system for a skin-worn transdermal patch device containing residual amount of an abusable opioid substance after use thereof on a patient, said system comprising:
- (a) a disposal container separate from and independent of said skin-worn patch device and having an opening therein for receiving said skin-worn patch device;

- (b) a deactivation system in said container comprising material that deactivates and renders unusable said abusable opioid substance on contact, comprising:
- (1) a first amount of carbon in an activated state in a quantity sufficient to bind said abusable opioid substance in said patch;
- (2) a second amount of carbon that has been pre-incorporated with a species that is releasable from said second amount of carbon upon solvent extraction and wherein said species is selected from the group consisting of capsaicin, ipecac, naloxone and naltrexone and combinations thereof such that said species remains with said abusable opioid substance upon extraction thereby rendering said abusable opioid substance unusable; and
- (c) closure device for closing said disposal container thereby capturing said skin-worn patch device.

- 61 A system as in claim 60 wherein said container is in the form of a flexible pouch.
- 62 A system as in claim 60 wherein said closure device includes an adhesive seal.
- 63 A system as in claim 61 wherein said closure device includes an adhesive seal.
- 64 (Canceled).
- 65 A system as in claim 60 wherein said opioid abusable substance comprises fentanyl.
66. A disposal system as in claim 60 wherein extraction solvents are water, ethanol and combinations thereof.
- 67-78 (Canceled).

Art Unit: 1618

- 79 A disposal system as in claim 60 wherein said species includes capsaicin.
- 80 A disposal pouch for the deactivation of a used opioid transdermal patch comprising a deactivation system in said container comprising material that deactivates and renders unusable said abusable opioid substance on contact, comprising:
- (a) a first amount of carbon in an activated state in a quantity sufficient to bind said abusable opioid substance in said patch;
 - (b) a second amount of carbon that has been pre-incorporated with a species that is releasable from said second amount of carbon upon solvent extraction and wherein said species is selected from the group consisting of capsaicin, ipecac, naloxone and naltrexone and combinations thereof such that said species remains with said abusable opioid substance upon extraction thereby rendering said abusable opioid substance unusable; and
 - (c) a container in the form of a pouch.
- 81 (Canceled).

Reasons for allowance

2. The following is an examiner's statement of reasons for allowance: The closest prior art was that which was found in Marcenayac et al (US 2004/0146547) cited in the previous office action filed on 02/03/2010. The prior art teaches a disposable article to prevent the misuse of a transdermal dosage form having a reservoir housing a dye material as inactivating agent, but fails to teach disposable system containing a

Art Unit: 1618

container/pouch separate from and independent of skin-worm patch containing a first amount of carbon in an activated state in a quantity sufficient to bind opioid abusable substance and a second amount of carbon that has been pre-incorporated with a capsaicin, ipecac, naloxone or naltrexone and combination thereof as irritants, such that the irritants remains with opioid abusable substance upon extraction thereby rendering said opioid abusable substance unusable.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAGADISHWAR R. SAMALA whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. R. S./
Examiner, Art Unit 1618

/Michael G. Hartley/
Supervisory Patent Examiner, Art
Unit 1618